

§ 93.223 Research misconduct proceeding.

Research misconduct proceeding means any actions related to alleged research misconduct taken under this part, including but not limited to, allegation assessments, inquiries, investigations, ORI oversight reviews, hearings, and administrative appeals.

§ 93.224 Research record.

Research record means the record of data or results that embody the facts resulting from scientific inquiry, including but not limited to, research proposals, laboratory records, both physical and electronic, progress reports, abstracts, theses, oral presentations, internal reports, journal articles, and any documents and materials provided to HHS or an institutional official by a respondent in the course of the research misconduct proceeding.

§ 93.225 Respondent.

Respondent means the person against whom an allegation of research misconduct is directed or who is the subject of a research misconduct proceeding.

§ 93.226 Retaliation.

Retaliation for the purpose of this part means an adverse action taken against a complainant, witness, or committee member by an institution or one of its members in response to—

- (a) A good faith allegation of research misconduct; or
- (b) Good faith cooperation with a research misconduct proceeding.

§ 93.227 Secretary or HHS.

Secretary or HHS means the Secretary of HHS or any other officer or employee of the HHS to whom the Secretary delegates authority.

Subpart C—Responsibilities of Institutions

COMPLIANCE AND ASSURANCES

§ 93.300 General responsibilities for compliance.

Institutions under this part must—

- (a) Have written policies and procedures for addressing allegations of re-

search misconduct that meet the requirements of this part;

- (b) Respond to each allegation of research misconduct for which the institution is responsible under this part in a thorough, competent, objective and fair manner, including precautions to ensure that individuals responsible for carrying out any part of the research misconduct proceeding do not have unresolved personal, professional or financial conflicts of interest with the complainant, respondent or witnesses;

- (c) Foster a research environment that promotes the responsible conduct of research, research training, and activities related to that research or research training, discourages research misconduct, and deals promptly with allegations or evidence of possible research misconduct;

- (d) Take all reasonable and practical steps to protect the positions and reputations of good faith complainants, witnesses and committee members and protect them from retaliation by respondents and other institutional members;

- (e) Provide confidentiality to the extent required by § 93.108 to all respondents, complainants, and research subjects identifiable from research records or evidence;

- (f) Take all reasonable and practical steps to ensure the cooperation of respondents and other institutional members with research misconduct proceedings, including, but not limited to, their providing information, research records, and evidence;

- (g) Cooperate with HHS during any research misconduct proceeding or compliance review;

- (h) Assist in administering and enforcing any HHS administrative actions imposed on its institutional members; and

- (i) Have an active assurance of compliance.

§ 93.301 Institutional assurances.

- (a) *General policy.* An institution with PHS supported biomedical or behavioral research, research training or activities related to that research or research training must provide PHS with an assurance of compliance with this part, satisfactory to the Secretary.

§ 93.302

PHS funding components may authorize funds for biomedical and behavioral research, research training, or activities related to that research or research training only to institutions that have approved assurances and required renewals on file with ORI.

(b) *Institutional Assurance.* The responsible institutional official must assure on behalf of the institution that the institution—

(1) Has written policies and procedures in compliance with this part for inquiring into and investigating allegations of research misconduct; and

(2) Complies with its own policies and procedures and the requirements of this part.

§ 93.302 Institutional compliance with assurances.

(a) *Compliance with assurance.* ORI considers an institution in compliance with its assurance if the institution—

(1) Establishes policies and procedures according to this part, keeps them in compliance with this part, and upon request, provides them to ORI, other HHS personnel, and members of the public;

(2) Takes all reasonable and practical specific steps to foster research integrity consistent with § 93.300, including—

(i) Informs the institution's research members participating in or otherwise involved with PHS supported biomedical or behavioral research, research training or activities related to that research or research training, including those applying for support from any PHS funding component, about its policies and procedures for responding to allegations of research misconduct, and the institution's commitment to compliance with the policies and procedures; and

(ii) Complies with its policies and procedures and each specific provision of this part.

(b) *Annual report.* An institution must file an annual report with ORI which contains information specified by ORI on the institution's compliance with this part.

(c) *Additional information.* Along with its assurance or annual report, an institution must send ORI such other aggregated information as ORI may re-

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quest on the institution's research misconduct proceedings covered by this part and the institution's compliance with the requirements of this part.

§ 93.303 Assurances for small institutions.

(a) If an institution is too small to handle research misconduct proceedings, it may file a "Small Organization Statement" with ORI in place of the formal institutional policies and procedures required by §§ 93.301 and 93.304.

(b) By submitting a Small Organization Statement, the institution agrees to report all allegations of research misconduct to ORI. ORI or another appropriate HHS office will work with the institution to develop and implement a process for handling allegations of research misconduct consistent with this part.

(c) The Small Organization Statement does not relieve the institution from complying with any other provision of this part.

§ 93.304 Institutional policies and procedures.

Institutions seeking an approved assurance must have written policies and procedures for addressing research misconduct that include the following—

(a) Consistent with § 93.108, protection of the confidentiality of respondents, complainants, and research subjects identifiable from research records or evidence;

(b) A thorough, competent, objective, and fair response to allegations of research misconduct consistent with and within the time limits of this part, including precautions to ensure that individuals responsible for carrying out any part of the research misconduct proceeding do not have unresolved personal, professional, or financial conflicts of interest with the complainant, respondent, or witnesses;

(c) Notice to the respondent, consistent with and within the time limits of this part;

(d) Written notice to ORI of any decision to open an investigation on or before the date on which the investigation begins;